

Remarks

The Office Action dated June 24, 2008 has been reviewed. Claims 81-100 were pending in the application. Independent claims 81 and 95 have been amended to more clearly recite the inventive concepts therein. For the reasons set forth below, Applicant respectfully submits that the claims are in condition for allowance, and respectfully requests reconsideration and withdrawal of each and every rejection.

I. Amendments and Exemplary Support

Independent claims 81 and 95 have been amended to specify that the tubular sleeve “comprises a substantially-uniform braided sleeve that” exerts a pressure distributed over an elongate portion of the tube.

Applicant respectfully submits that the amendment adds no new matter. Support for the amendment can be found throughout the application as filed, for example, on page 11, lines 17-18 and page 13, lines 17-19. Additionally, FIGS. 4, 5, and 10 clearly illustrate a braided sleeve having a substantially-uniform braid.

II. Claims 81-100 are Non-Obvious and Patentable over Sobin and Delk

The Action rejected claims 81-100 under 35 U.S.C. §103(a) as being unpatentable over Sobin et al. (US 4,509,877) in view of Delk et al. (US 5,292,312).

Independent claims 81 and 95 are non-obvious under the factual inquiries of *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

A. Determining the scope and content of the prior art

Claims 81-100 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sobin et al. (US 4,509,877) in view of Delk et al. (US 5,292,312). Sobin is directed to a “tapered torque strain relief coupling.” Delk is directed to a “universal lumen catheter holder.”

B. Ascertaining the differences between the claimed invention and the prior art

As recognized by the Office, Sobin fails to disclose "a medical or surgical fastener" having "attachment means for attaching the sleeve to a patient". The sleeve of Sobin is not intended for attachment of the flexible member to the rigid member, but to the reduction of torque or bending stresses in the flexible member. *See e.g.*, col. 4, lines 3-9. Instead, Sobin teaches that the cable 1 (flexible member) is attached to the plug 3 (rigid member) by means of a clamp 5. *See* FIG. 1; col. 4 lines 39-44. As such, there is no suggestion that the braided portion of Sobin's device could be configured to aid in attaching the cable to the plug.

Further, Sobin fails to disclose or suggest a substantially-uniform braided sleeve that exerts a pressure distributed over an elongate portion of the tube. Instead, Sobin teaches a flexible member with a weave that varies along its length. For example, Sobin teaches that "the end of a flexible member, at its point of attachment to a rigid member, is enclosed within a plurality of braided strands . . . [that] are very closely or narrowly woven at the point of attachment, and are more openly or widely woven as the distance from the point of attachment increases." Col. 3, lines 47-52.

Delk fails to cure the deficiencies of Sobin. Specifically, Delk also fails to teach the a substantially-uniform braided sleeve that" exerts a pressure distributed over an elongate portion of the tube. In fact, Delk does not disclose a braided sleeve of any form. As such, any combination of Sobin and Delk would fail to disclose or suggest every feature of the claims.

C. Resolving the level of ordinary skill in the art

As noted in the last response, since the claimed fastener is a medical or surgical fastener, Applicant respectfully submits that a person of ordinary skill in the pertinent art could have been a medical practitioner, such as a doctor. Such a person could have been aware of the previous mechanisms for securing a tube to a patient, such as the adhesive tape bridges and other devices disclosed on pages 2-7 of the present application.

D. Teaching / Suggestion / Motivation To Modify or Combine References

The cited art provides no teaching, suggestion, or motivation to modify the cited references to include every element of the claimed invention. Applicant is mindful that the teaching, suggestion, motivation test (TSM test) is not the only test for analyzing obviousness and that courts should apply the test flexibly; however, the TSM test remains “the primary guarantor” against hindsight analysis, which appears to be present in the current Office Action:

As this court has explained, however, a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis such as occurred in this case. In re Translogic Tech., Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007) (“[A]s the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention.”). The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of evidence – teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires.

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., No. 2007-1223, slip op. at 11 (Fed. Cir. Mar. 31, 2008).

As discussed above, neither of the cited references teaches or suggests a substantially-uniform braided sleeve that exerts a pressure distributed over an elongate portion of the tube, as required by each of independent claims 81 and 95. As such, it is simply not possible to combine elements from the cited references, or to substitute one element from Delk for an element from Sobin, to arrive at the claimed invention. Further, due to the dissimilarities of the Sobin and Delk references, a person of ordinary skill in the art would not seek to combine their teachings.

Sobin is specifically concerned with “strain relief” at the attachment point, particularly from “stresses resulting from application either of torque (twisting force) or of bending (flexing) force or both.” Col. 4, lines 5-7. As discussed above, attachment of the flexible member and the rigid member is provided by a separate “clamp 5 held by bolt 4.” Col. 4, line 41, which is of substantially-different construction than the claimed fastener. Therefore, a person having ordinary skill in this art, would not look to the disclosure of Sobin to provide a fastener for attachment of a tube to a patient. Even if a person of ordinary skill did turn to its disclosure, Sobin teaches directly away from providing a substantially-uniform braid, as the whole purpose of Sobin is to provide support of variable stiffness along the length of the flexible member. In

particular, Sobin teaches that the sleeve of variable weave described is superior to any other type of braid, as set out in column 3, line 52 - column 4, line 2 (emphasis added):

“At the point of attachment, the strands are spaced very close together and are nearly perpendicular to the flexible member, and at that point the braid is so stiff that its stiffness is just about equal to the stiffness of the rigid member itself. As the distance along the flexible member from the point of attachment increases, the weave of the braid becomes progressively more wide or open, and at the point of termination of the braid the stiffness of the braid has decreased so much that the stiffness of the combination of the braid and the flexible member is about the same as the stiffness of the flexible member by itself. In this fashion, stresses which would otherwise be concentrated at the point of attachment, and which would cause the breakage or failure of the flexible member, **are by said structural design of the braid progressively distributed or tapered along the length of the flexible member** so that the member can flex and “give” with the stress as distributed.”

In short, Sobin teaches that its varied weave is what enables its device to function as claimed by allowing stresses caused by the attachment of the flexible member to the rigid member to be distributed, in a tapered manner, along the flexible member. There is no teaching or suggestion within the cited references, nor has any motivation been identified, that would lead a person of ordinary skill in the art to derive the claimed invention from the teachings of the cited references. As such, the claims are non-obvious over Sobin in view of Delk because Sobin teaches away from a substantially-uniform braided sleeve, as required by independent claims 81 and 95.

Further, when a proposed modification would render the prior art unsuitable for its stated purpose, there is no suggestion or motivation to make the modification. MPEP § 2143.01(V); *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Sobin is concerned with “strain relief” at the attachment point, particularly from “stresses resulting from application either of torque (twisting force) or of bending (flexing) force or both.” Col. 4, lines 5-7. Sobin is directed to creating a tapered distribution of such forces along the length of its device, and explicitly describes this purpose in its description of the tapered nature of the braid: “its stiffness gradually decreases as the distance from the point of connection increases.” Col. 6, lines 10-11 (emphasis added). Modification of Sobin to include a substantially-uniform braid would result in a braid having substantially-uniform properties along its length, and would render the device unsuitable for performing Sobin’s only purpose – tapered distribution of forces. As such, modification of Sobin to include a substantially-uniform braid, as required by claims 81 and 95, is improper.

Delk fails to supply the deficiencies of Sobin. As noted above, Delk does not disclose, or even suggest, a braided tubular sleeve. As such, a person of ordinary skill could not introduce this feature based on the teaching of Delk.

No combination of the cited references would include every element of independent claims 81 and 95; a person of ordinary skill in the art would not be motivated to combine or modify the references; and modification of Sobin is improper. Independent claims 81 and 95 are therefore non-obvious and patentable under 35 U.S.C. § 103 over Sobin, alone or in view of Delk. Claims 82-94 and 96-100 depend from claims 81 and 95, respectively; and as such, are non-obvious at least for the reasons stated above. Additionally, Applicant respectfully submits that that the dependent claims add further novel and non-obvious features.

For at least the reasons discussed above, Applicant submits that claims 81-100 are in condition for allowance, and respectfully requests reconsideration and withdrawal of each and every rejection.

III. Conclusion

The foregoing is intended to be a complete response to the Office Action dated June 24, 2008. Applicant respectfully submits that the claims are in condition for allowance. The Examiner is invited to contact Applicant's agent at (512) 536-3083 with any comments or questions in order to expedite the resolution of any remaining issues.

Respectfully submitted,



Eagle H. Robinson
Reg. No. 61,361
Agent for Applicant

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
Telephone: 512/536-3083
Facsimile: 512/536-4598

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